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Jacqueline Kurth, Manager Medical Resource Office 800 West Washington Street Phoenix, Arizona 85007

Dear Ms. Kurth:

I appreciate this opportunity to comment on the white paper provided to the ICA on July 11, 2018 by the Public Consulting Group. I am a general surgeon in private clinical practice in metropolitan Phoenix since 1981 and have served in leadership roles in the Arizona Medical Association and Maricopa County Medical Society. I am a past Diplomate of the American Board of Surgery and a Fellow of the American College of Surgeons. I also am a Senior Fellow at the Cato Institute in Washington, DC, where I engage in public policy scholarship and analysis in the Department of Health Policy Studies and the Center for the Study of Science. In addition, I am a Visiting Fellow at the Goldwater Institute in Phoenix. Based on my extensive experience in clinical practice as well as public policy research I am comfortable offering my comments.

The white paper's critiques of physician dispensing rely heavily on old data (from 2007 to 2011) from states with different regulatory regimes than those in Arizona and therefore largely makes "apples to oranges" comparisons. Some of the concerns raised by the authors have been addressed in recent years and therefore need to be reconsidered.

For example, since 2014, as the great majority of health care practitioners have adopted Electronic Health Records programs, concerns about possible drug interactions have become a thing of the past. EHR programs have built-in drug interaction warnings to alert providers who e-prescribe within patients' medical records, erring on the side of precaution, and requiring prescribers to override the warning before the prescription can go through.

Prescription Drug Monitoring Programs had not been in wide use during the period ranging from 2007 to 2011, and PDMPs vary from state to state. Arizona's PDMP required reporting by pharmacies beginning in the year 2008 and started collecting and tracking practitioners' data in 2009. Revisions to the law took effect in April of this year requiring practitioners to consult the PDMP data base and placing limits on dosage and amount of controlled substances that may be prescribed.

Public policy regarding the prescription of controlled substances is an area in which I have considerable scholarship and expertise. As you are aware, most of the limitations on the numbers and dosages of prescription opioids imposed by state legislatures and monitored by PDMPs are based upon the opioid prescribing guidelines published by the Centers for Disease Control and Prevention in 2016. The CDC stated in those guidelines that they were not intended to be "prescriptive" and that they were for the most part based on "type 4 evidence," which "indicates that one has very little confidence in the effect estimate, and the true effect is likely to be substantially different from the estimate of the effect." Numerous academic researchers and pain and addiction specialists have criticized these guidelines for not being evidence-based. In fact, recognizing the criticisms of the CDC guidelines, on August 22, 2018 Commissioner Scott Gottlieb of the Food and Drug Administration announced plans to contract with the National Academy of Sciences, Engineering, and Medicine (NASEM) to develop "evidence-based, indication-specific guidelines to help guide appropriate prescribing of opioid analgesics."

The implementation of PDMPs is largely responsible for the dramatic decrease in the opioid prescription rate since 2010. The CDC reported a 41 percent decrease in the prescription of high-dose (90 morphine milligram equivalents or greater) opioids between 2010 and 2016, and recent research shows that dropped another 16.1 percent in 2017. Many prescribers, reading press reports of doctors arrested and prosecuted for "over-prescribing" opioids, have over-compensated and, out of fear, have adopted a practice of under-prescribing pain medication, or abandoning the prescribing of opioids entirely. Many major pharmacy chains, some them targets of state and municipal litigation initiatives, have voluntarily announced they will limit their dispensing of prescription opioids to just a five days' supply, and some are refusing to fill patients' prescriptions.

Despite this fact, the opioid-related overdose rate continues to climb as non-medical users migrate to more dangerous heroin and fentanyl. But the unintended collateral damage of this policy has been that many chronic pain patients, finding themselves cutoff or abruptly tapered from their pain medication, have turned in desperation to the black market (and the attendant risk of heroin and fentanyl exposure), and many have turned to suicide. These reports about desperate patients resorting to illicit drugs or suicide are the reason why the US Senate is poised to pass a bill this week addressing the opioid problem that "would require HHS and the Department of Justice to conduct a study on the effect that federal and state opioid prescribing limits have had on patients — and specifically whether such limits are associated with higher suicide rates."

On numerous occasions over the past several months I have received calls from my recent postoperative patients who had been discharged from the hospital by the hospitalist after a major painful operation with only a half-dozen prescription pain pills. They have had to come to my office in order for me to prescribe them enough medication to sustain them through the recovery period. This is all a result of the fear of

opioid prescribing perpetrated by the PDMPs amid reports of prosecutions for overprescribing.

This unintended harm inflicted on pain patients by PDMPs is precisely why it is important to allow providers who treat chronic pain patients to be able to dispense opioids. While the majority of such providers will, out of fear, continue to curtail their prescribing of opioids, many providers who know their patients well and understand what it takes to control their pain will courageously dispense the pain medication to their patients—who might otherwise be unable to get them filled at a pharmacy—still complying with Arizona PDMP requirements, and help their patients get needed relief more quickly.

While there are valid concerns about the long-term consequences of opioids on disability and employment rates, studies on this matter are inconclusive. For example, a March 2018 National Bureau of Economic Research working paper by researchers at Princeton University found "the estimated effect of opioids on employment-to-population ratios is positive but small for women, but there is no relationship for men," and "opioids may allow some women to work who might otherwise leave the labor force." It concluded there is "no simple causal relationship between economic conditions and the use of opioids."

There are many advantages to patients when health care providers are allowed to dispense medications to patients. The ability to get needed relief without delay, and without the inconvenience and time investment of travelling to a pharmacy, where some patients might be denied medication, are obvious ones.

I wish once again to thank the Industrial Commission for allowing me the opportunity to comment on this matter.

Respectfully,

Jeffrey A. Singer, MD, FACS

<sup>&</sup>lt;sup>1</sup> https://www.cato.org/people/jeffrey-singer

<sup>&</sup>lt;sup>2</sup> https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

<sup>&</sup>lt;sup>3</sup> https://www.tandfonline.com/doi/full/10.1080/08897077.2017.1345194

<sup>&</sup>lt;sup>4</sup> https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm617908.htm

<sup>&</sup>lt;sup>5</sup> https://www.businesswire.com/news/home/20180419005342/en/IQVIA%E2%84%A2-Institute-Human-Data-Science-Study-U.S.

<sup>&</sup>lt;sup>6</sup> https://www.politico.com/story/2018/09/06/senate-opioid-response-package-762537

<sup>&</sup>lt;sup>7</sup> http://www.nber.org/papers/w24440.pdf